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Docket No. 1225\0C674US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David BERD

Serial No.: 08/203,004

Group Art Unit: 1642

Filed: 02/28/94

Examiner: Susan Ungar

For: COMPOSITION AND METHOD OF USING TUMOR CELLS

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RESPONSE TO ELECTION REQUIREMENT  
& PETITION UNDER 37 C.F.R. § 1.129(b)(2)

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

March 11, 1999

Sir:

In response to the Election Requirement mailed in this patent application on February 1, 1999, please consider the following Response and the Petition.

The present application was filed on February 28, 1994, and claims the benefit under 35 U.S.C. §120 from the parent applications: U.S. Application Serial No. 07/985,334 filed December 4, 1992 (now U.S. Patent No. 5,290,551), and U.S. Application Serial No. 07/520,649 filed May 8, 1990. Thus, having been pending for at least two years prior to June 8, 1995, the

present application is entitled to the transitional procedure under 37 C.F.R. §1.129(a). A response under this Section was filed on December 3, 1998.

In response to the December 3, 1998 Amendment, the Examiner has issued an Election Requirement mailed February 1, 1999. In the Requirement, the Examiner has requested election of species among (i) tumor types (melanoma, lung, colon etc.), and (ii) hapten types (DNP, TNP, AED). Applicant respectfully submits that this Election Requirement was not proper in view of the fact that the present application is entitled to the transitional restriction procedure under 37 C.F.R. §1.129(b) for the reasons outlined in more detail below. *See* MPEP §803.03.

Section 803.3 indicates that the restriction procedure under 37 C.F.R. §1.129(b) applies to *both* restriction requirements under 37 C.F.R. §1.142 and election of species requirements under 37 C.F.R. §1.146. Accordingly, 37 C.F.R. §1.129(b) and MPEP §803.03 are applicable to the present Election of Species Requirement. Referring to the scheme regarding the transitional restriction practice under 37 C.F.R. §1.129(b), which scheme is provided in the MPEP §803.03 (page 800-8, 7<sup>th</sup> edition, copy attached at tab 1), an election of species requirement cannot be made in this application because:

- (i) the application was filed before June 8, 1995;
- (ii) the application has an effective filing date of earlier than June 8, 1992 (the effective filing date is May 8, 1990);

- (iii) the Election Requirement with respect to the species of tumor cells and/or the species of haptens was *not* made in this application or either of the parent applications prior to April 8, 1995; and
- (iv) the fact that Election Requirement was not made prior to April 8, 1995 was *not* due to actions by the applicant (for the reasons outlined below).

With respect to point (iii) above, a Restriction Requirement was made in the grandparent application Serial No. 07/520,649 filed May 8, 1990 in which the pending claims were restricted to a number of invention groups. *See* the Official Action mailed September 30, 1991 (copy attached at tab 2 hereto). However, election of species requirement was not made in that application although the claims were drawn to any tumor (original claims 1, 11, and 23 of the '649 application), any hapten (original claims 1, 11, and 23 of the '649 application), and enumerated hapten species (original claims 3, 13, and 26 of the '649 application). No further Restriction or Election Requirement was made in this or either of the two parent applications, although claims enumerating species of tumor cells and hapten were subsequently pending.

Referring to point (iv) above, none of the applicant's actions prevented an Election Requirement to be imposed. The claims as originally filed in the grandparent application were broadly written to any human cancer and any hapten.

For the above reasons (i)-(iv), and referring to the MPEP §803.03 scheme, this application is entitled to the transitional restriction practice under 37 C.F.R. §1.129(b), and the applicant should have been given a time period to either:

- (i) elect and pay fee set forth in 37 C.F.R. §1.17(f) for each additional species

over one; or

(ii) file a petition under 37 C.F.R. §1.129(b)(2) traversing the Election Requirement.

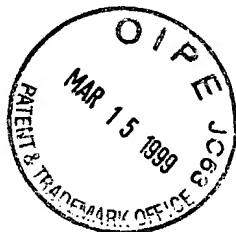
The applicant hereby files a Petition to traverse the requirement on the ground that no additional search would be required to continue the examination of claims directed to enumerated species of tumor cells or hapten. No fee is believed to be due. However, should the Commissioner find that the fee is due, he is authorized to charge the fee to Deposit account No. 04-0100.

According to the MPEP §803.03, the petition may be filed without making an election. Thus, a species election has not been made herein.

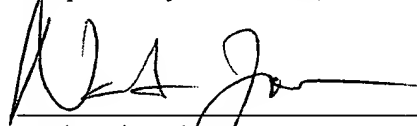
In the December 3, 1998 Response to the Advisory Action mailed September 11, 1998, applicant has canceled a number of claims and added new claims 49-76. From the claims pending in the application prior to the December 3, 1998 Response, claims 43, 44 and 47 were maintained. Claims 43, 44, 47, and 76 are the only pending independent claims and dependent claims 49-75 have been added to further define specific embodiments within the scope of these independent claims. The pending claims are now subject to the Election of Species Requirement with respect to the tumor cell type and the hapten type. However, these claims were subject to prior examination in this application and prior art search with respect to them and underlying species was already conducted. For example, the claims in this application were rejected by the Examiner in view of, *inter alia*, references teaching conjugating TNP to mouse tumor cells (Fujiwara, J. Immunol., 1980, 124:863), conjugating DNP to human tumor cells (Berd *et al.*,

Proc. Am. Assoc. Cancer Res., 1989, 30:382), treating melanoma with non-haptenized melanoma cells (Berd *et al.*, Cancer Res., 1986, 46:2572-77), and treating metastatic renal carcinomas with non-haptenized renal carcinoma cells (McCune *et al.*, Cancer 1981, 47:1984-87 and McCune *et al.*, Cancer 1979, 43:1619-23.) (These references were addressed in the December 3, 1998 Amendment). Accordingly, in view of the fact that the independent claims 43, 44 and 47 have already been examined in view of more than one tumor cell species and more than one hapten species, no further search appears to be necessary. With respect to dependent claims added by the December 3, 1998 Amendment, these claims correspond to cancelled claims 2, 3, 5-7, 10, 24-28, 34-35, and 37-38. These claims were rewritten to depend from the claims 43, 44, and 47 and were presented in a new-claim format for clarity. Thus, the subject matter of claims 49-75 was previously searched and under examination. Finally, with respect to new independent claim 76, this claim encompasses the same species that were already searched. For these reasons, applicant believes that the election requirement should be withdrawn.

Reconsideration of this application and withdrawal of the Election Requirement is respectfully requested.



Respectfully submitted,

  
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